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(54) **Radiopaque catheter**

Strahlenundurchlässiger Katheter

Cathéter radio-opaque

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(73) Proprietor: **Cook Incorporated**
Bloomington IN 47402-0489 (US)

(72) Inventors:
• **Drewes Jr., David A.**
Bloomington, Indiana 47404 (US)

• **Parker, Fred T.**
Unionville, Indiana 47468 (US)

(74) Representative:
Johnston, Kenneth Graham
5 Mornington Road
Woodford Green Essex, IG8 OTU (GB)

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Description

[0001] This invention relates to radiopaque catheters.

[0002] Radiopaque catheters are used to provide visualization of the catheter during a therapeutic procedure such as PTCA or kidney stone removal. They are also used in diagnostic imaging procedures for injecting contrast medium into the body of a patient. Several commercially available radiopaque catheters include increased radiopacity about the distal catheter end. Visualization of the end is critical for locating the catheter end with respect to anatomical structures and preventing inadvertent trauma or injury of a vessel or duct during advancement of the catheter.

[0003] One approach to providing a curved, radiopaque catheter is to form the catheter body from a compound of a polyurethane material with either 20 weight percent of barium sulfate or 33.5 weight percent of bismuth subcarbonate. The distal catheter tip is formed from a compound of a polyurethane material with 49.83 weight percent of bismuth trioxide. As a result, the curved catheter body is slightly radiopaque, and the distal catheter tip is more radiopaque than the curved body.

[0004] A problem with this catheter is that the compound material forming the distal catheter tip is only moderately radiopaque in comparison to highly radiopaque materials such as solid platinum, gold, or tungsten. As a result, the radiopacity of the distal catheter tip indicates the general position thereof. However, the position of the curve in the catheter body cannot be readily discerned. Furthermore, the point at which the curved catheter body ends and the distal catheter tip begins has no readily imageable boundary. Another problem with this curved catheter is that visualization of the slightly or moderately radiopaque catheter materials is deemphasized or overcome by the images of surrounding tissues. The problem is compounded when injecting contrast medium into a blood vessel or another duct of a patient's body via the curved catheter. The contrast medium flows into the vessel or duct and surrounds the curve and the distal tip of the catheter. As a result, the curve and the distal tip of the catheter are difficult to discern or are completely obstructed by the bright image of the contrast medium.

[0005] Yet another problem with this curved catheter is that safely steering and maneuvering the catheter through tortuous vessels or ducts requires precise visualization of the distal catheter tip. When the precise position of the curve or the distal tip of the catheter is not visible, the catheter can be inadvertently advanced into anatomical structures. As a result, tissue is injured or punctured. When imaging a coronary artery or a ventricle of the heart, such trauma or injury results in serious complications and bleeding.

[0006] In view of these problems, an attempt was made to increase the radiopacity of the curved catheter by providing a plastic formulation with a higher than 75 weight percent of a radiopaque agent. This known

attempt resulted in failure due to the brittleness of the plastic catheter material. Furthermore, the plastic catheter material exhibited a general loss of the desired softness and flexibility.

[0007] U.S.-A-504 5072 describes a catheter as defined in the preamble of claim 1.

[0008] According to the present invention there is provided a catheter as defined in claim 1.

[0009] The foregoing problems are solved and a technical advance is achieved in an illustrative flexible, radiopaque catheter containing either a thermoplastic elastomer, or a thermoplastic material, or melt processible rubber with a moderately radiopaque proximal tubular member portion and a highly radiopaque distal tubular member portion which contains greater than 75 weight percent of a radiopaque agent. As a departure in the art, the distal tubular member portion can be a thermoplastic material with a greater than 75 weight percent loading of a radiopaque agent.

[0010] In both instances the distal member is flexible and softer in durometer than the proximal portion of the catheter. The distal tubular member portion of the preferred catheter advantageously includes a homogeneous composition containing 20 weight percent of a base thermoplastic, elastomer material, preferably a polyether block amide, or a thermoplastic elastomer, and more than 75 weight percent radiopaque agent, preferably tungsten. The flex modulus of the base thermoplastic, elastomer material is preferably in a range of 23,000 to 75,000 pounds per square inch. The distal tubular member portion of the catheter is lower in durometer than that of the proximal tubular member portion. The distal tubular member portion advantageously exhibits a composite durometer of approximately 47 on the Shore D scale.

[0011] The flexible plastic angiographic catheter comprises an elongated member having a passage therein. The distal portion of the elongated member comprises a first, flexible, radiopaque plastic material of a homogeneous composition containing by weight greater than 75 percent of a first radiopaque agent. The weight percent range of the radiopaque agent ranges from 75 to 100% and preferably from 75 to 95 percent. The homogeneous composition includes a base thermoplastic, elastomer material from a group consisting of a polyether block amide and a polyamide terpolymer material and a first radiopaque agent from a group consisting of tungsten, platinum, gold, silver, lead, and tantalum. The durometer of the base thermoplastic, elastic material is in a range of 25 to 72 on the Shore D scale.

[0012] The proximal portion of the elongated member comprises a flexible, radiopaque material of a base thermoplastic material from a group of materials listed below, and a radiopaque agent from a group comprising bismuth oxychloride, bismuth subcarbonate, bismuth trioxide, barium sulfate, and tungsten, and other materials also listed below.

[0013] As a result, this flexible plastic material catheter

ter advantageously includes a highly radiopaque distal tubular member portion which is highly visible radiographically while still maintaining a high degree of flexibility and softness for introduction to the angiographic site. Even with an extremely high loading of a radiopaque agent, the distal tubular portion retains its material integrity while still remaining soft and flexible. The use of a high density radiopaque agent, such as tungsten in combination with a base thermoplastic, elastomer material, also advantageously contributes to the material integrity of the soft and flexible distal tubular member portion.

Brief Description of the Drawing

[0014]

FIG. 1 depicts a longitudinal view of an illustrative angiographic catheter of the present invention with a preformed pigtail configuration in the highly radiopaque, distal portion; and

FIG. 2 depicts a partially sectioned, longitudinal view of the catheter of FIG. 1 at the bond between the moderately radiopaque proximal portion and the highly radiopaque distal portion.

Detailed Description

[0015] FIG. 1 depicts a longitudinal view of an illustrative flexible plastic, angiographic catheter 10 which is an elongated member with moderately radiopaque proximal tubular member portion 11 and highly radiopaque, distal tubular member portion 12 fixedly attached thereto at thermal bond 13. highly radiopaque distal tubular member portion 12 is formed from a flexible, highly radiopaque plastic material 14 comprising, for example, a homogeneous and uniformly dispersed composition of a base thermoplastic elastomer material and a radiopacifying agent. Flexible, highly radiopaque plastic material 14, as depicted in FIG. 2, is preferably formed of approximately 20 weight percent of a base thermoplastic, elastomer material and 80 weight percent of a radiopacifying agent. When catheter 10 is introduced into the vascular system of a patient through a commercially available access sheath, the catheter is advanced over a wire guide through the vessels of a patient until the highly radiopaque, distal portion is positioned at a desired angiography site. Catheter 10 includes distal end 15 with preformed loop or pigtail configuration 16 positioned proximately for atraumatic positioning of the catheter past anatomical structures such as the tricuspid valve of the heart.

[0016] Catheter 10 further includes proximal end 17 with connector cap 18 and female Luer lock connector 19 positioned thereabout for grasping by the physician and manipulation of the catheter. Catheter 10 also further includes passage 20 extending longitudinally therein between proximal end 17 and distal end 15.

When the highly radiopaque, distal portion is positioned at the desired angiography site, a well-known syringe (not shown) filled with contrast medium is connected to Luer lock connector 19. The contrast medium is injected to the angiography site via passage 20. The contrast medium exits passage 20 at sideports 21 and end port 22, which are formed in the highly radiopaque, distal portion of the catheter.

[0017] FIG. 2 depicts a partially sectioned, longitudinal view of the catheter of FIG. 1 at thermal bond 13 where moderately radiopaque proximal portion 11 is fixedly attached to highly radiopaque distal portion 12 formed from flexible, highly radiopaque plastic material 14. The highly radiopaque distal portion extends for a sufficient length of the catheter to include a loop or pigtail configuration 16 and sideports 21 for brightly imaging and positively visualizing the position of the catheter during advancement to the desired site and the subsequent injection of contrast medium.

[0018] Proximal tubular member portion 11 of catheter 10 is, for example, an approximately 100 cm length of flexible, moderately radiopaque, plastic material 23 with a (.067") 0.17cms, outside diameter (5 French) and a (.050") 0.127cms, inside diameter, which exhibits sufficient pushability for advancing the catheter to a desired site. The flexible, moderately radiopaque, plastic material 23 comprises a base thermoplastic, elastomer material and a radiopaque agent in a weight percent range of 15 to 40. The base thermoplastic, elastomer material preferably comprises a polyamide elastomer such as a commercially available elastomeric nylon 12 material. Alternative base thermoplastic, elastomer materials are from a group consisting of polyester elastomers, polyurethanes, and a polyether block amide. The radiopaque agent preferably comprises 25 weight percent of bismuth oxychloride, which is easily dispersible through the base thermoplastic, elastomer material and exhibits very good surface characteristics. Bismuth oxychloride is also white in color, which allows the catheter to assume a number of different colors with the addition of a coloring pigment. Alternative radiopaque agents are from a group consisting of bismuth subcarbonate, bismuth trioxide, barium sulfate, and tungsten.

[0019] Distal tubular member portion 12 of catheter 10 is, for example, an approximately 8-9 cm length of flexible, highly radiopaque, plastic material 14 with a 0.168cms (.066") outside diameter (5 French) and a 0.114cms (.045") inside diameter, which is softer and more flexible and has a respective durometer lower than that of the proximal tubular member portion. Flexible, highly radiopaque, plastic material 14 comprises a homogeneous and uniformly dispersed composition of a base thermoplastic, elastomer material and a high density radiopaque agent in a weight percent range of 75 to 100. The high density radiopaque agent has a density in excess of 10 grams per cubic centimeter and is preferably from a group consisting of tungsten, platinum, gold, silver, lead, and tantalum. Tungsten with a

density of 19.29 grams per cubic centimeter is preferred due to its availability and relative low cost.

[0020] The homogeneous and uniformly dispersed composition of plastic material 14 includes approximately 20 weight percent of a base thermoplastic, elastomer material such as a polyether block amide with a durometer of 40 on the Shore D scale, which is commercially available from Elf Atochem North America of Birdsboro, Pennsylvania, or a polyamide terpolymer with a durometer of 40 on the Shore D scale, which is commercially available from Huls America of Piscataway, New Jersey. The base thermoplastic, elastomer material can have a durometer in a range of 25 to 72 on the Shore D scale. With 80 weight percent tungsten, the composite durometer of preferred distal tubular member portion 12 is approximately 47 on the Shore D scale. The flexibility of the preferred base thermoplastic elastomer material exhibits a flex modulus in a range of (23,000 to 75,000 pounds per square inch.) 161×10^6 to 525×10^6 Pascals.

[0021] As previously suggested, the homogeneous and uniformly dispersed composition of plastic material 14 further includes approximately 75 to 100 weight percent of a radiopacifying agent such as high purity, micronized tungsten powder (40 micron), which is commercially available from Atlantic Equipment Engineers of Bergenfield, New Jersey. Tungsten is compounded with a base thermoplastic, elastomer material at a weight percent in a range from 75 to 100. The required volume of tungsten is small enough to allow the desirable physical characteristics of the base material to be exhibited. The distal portion of the catheter exhibits softness and flexibility for atraumatic insertion to the desired angiographic site.

[0022] Catheter 10 is preferably shipped and stored without exposure to high temperatures in a hermetically sealed package that is nonpermeable to light for preventing degradation of flexible, highly radiopaque plastic material 14.

[0023] Flexible, highly radiopaque plastic material 14 is formed by, for example, drying the base thermoplastic elastomer material to a moisture content below .025 percent. The dried, pelleted base material is loaded into a pellet feeder, and the tungsten powder is loaded into a powder feeder of a feeder system attached to a commercially available, corotating twin screw machine from, for example, Werner Pfleiderer Corporation of Ramsey, New Jersey, or American Leistritz Corporation of Somerville, New Jersey. The feeder system preferably has an accuracy of 2 percent by weight or better and is commercially available from, for example, K-Tron Corporation of Pitman, New Jersey, or Thayer Scale of Pembroke, Massachusetts. The twin screw machine is heat soaked for a time period such as 15 minutes. The pellet feeder is started first, and the melt quality of the material is visually verified to be certain that the material is clean, clear, smooth, and free of any internal bubbles. Then the powder feeder is started, and the melt quality

of the compounded material is visually verified to be certain that the material is solid black and has no lumps apparent without magnification. After the melt quality appears to be acceptable, the machine is allowed to run for about 5 to 10 minutes before starting the extrudate through a water cooling trough such as is commercially available from Werner Pfleiderer or American Leistritz, as listed above, and a strand pelletizer such as is commercially available from ConAir Jetro of Bay City, Michigan, or American Leistritz, as listed above. Finally, the compounded material is processed through a conventional, commercially available, single screw extruder with the appropriate tooling and ancillary equipment for yielding an approximately 8-9 cm length of highly radiopaque distal tubular member portion 12, which has a (0.066") 0.168cms, outside diameter (5 French) and a (.045") 0.114cms, inside diameter.

[0024] Pigtail 16 is, for example, 1.3 cm in diameter. Alternative atraumatic distal end configurations such as open loops and pigtails oriented transversely with respect to the axis of the catheter are contemplated. Sideports 21 are, for example, 0.081cms, (.032") in diameter. Bond 13 is positioned in a range between 4.5 and 5.5 cm proximal the distal-most point on the preformed pigtail surface when measuring along the axis of catheter 10. Bond 13 is formed by heat, but other methods of bonding such as the use of adhesive or mechanical means are contemplated.

[0025] It is to be understood that the above-described angiography catheter with a highly radiopaque distal portion is merely an illustrative embodiment of the principles of this invention and that other radiopaque catheters may be devised by those skilled in the art. For example, guiding catheters, angioplasty balloon catheters, drainage catheters, and any other medical catheter that desirably includes a highly radiopaque portion are contemplated. It is further contemplated that the catheter include one or more preformed curves and bends along the axis thereof for facilitating introduction into various blood vessels or ducts with well-known anatomical curvatures. It is also further contemplated that the highly radiopaque material include a stabilizer package having one or more antioxidant chemicals, which result in heat stabilization, and one or more ultraviolet stabilizing chemicals, which protect the material from light degradation, in order to extend the shelf life of the catheter.

[0026] Preferred forms of thermoplastic materials, elastomer materials or mixtures which may be used in preferred embodiments of the present invention are as follows:-

1. THERMOPLASTIC STYRENIC BLOCK ELASTOMERS

[0027]

- A. S-B-S (STYRENE-BUTADIENE-STYRENE)
- B. S-EB-S (STYRENE-ETHYLENE, BUTYLENE-

STYRENE)**C. S-I-S (STYRENE-ISOPRENE-STYRENE)**

TRADENAMES: Kraton, Finaprene, Solprene, Europrene, C-Flex Elexar

MANUFACTURERS: Shell, Fina, Phillips, Concept Polymers

These materials can be used straight from the manufacturer or compounded in with just about any thermoplastic material, such as nylon or polyolefins, to impart flexibility and impact resistance.

2. THERMOPLASTIC POLYOLEFIN ELASTOMERS

These are mechanical blends or alloys of various thermoplastic polyolefins and thermoplastic rubbers such as EPR (ethylene-propylene-rubber) or EPDM (ethylene-propylene-diene-monomer).

Typical thermoplastic polyolefins that would be used in this application are: LDPE, LLDPE, MDPE, HDPE, PP, EVA, EMA, EMMA, AND EEA.

The EPR or EPDM would impart flexibility to the thermoplastic polyolefin when combined with it.

3. POLYVINYLCHLORIDE

PVC when compounded with various plasticizers can be manufactured in various hardnesses and flexibilities. Plasticizers used for medical applications are generally of the non-phthalate type in order to minimize extractability. The amount of plasticizer contained in the compound determines its hardness or flexibility. The greater the amount of plasticizer the softer and more flexible the compound.

4. POLYOLEFINS

Polyolefins are available in a variety of densities which affect the materials hardness and flexibility. The lower the density the more flexible the compound. However, the higher density materials could easily be compounded with an elastomeric material to increase its flexibility.

Typical polyolefins are: LDPE, LLDPE, MDPE, HDPE, ULDPE, EVA, EMA, EEA and EMMA.

These materials could be used straight from the manufacturer or can be compounded with elastomeric materials such as the styrenic block or melt processible rubbers.

5. POLYAMIDES (NYLON)

Polyamides are typically rigid materials. However, these materials can be compounded with elastomeric type materials to impart a degree of flexibility. A compound of polyamide and elastomeric material would be considered to be a mechanical blend or alloy, similar in nature to a TPO (Thermoplastic PolyOlefin Elastomer).

6. MELT PROCESSIBLE RUBBER

Melt processible rubber can be used as is straight from the manufacturer or can be compounded into just about any other thermoplastic to impart flexibility.

Tradename: Alcryn, Santoprene

Claims**1. A flexible plastic catheter (10) comprising:**

an elongated member having a passage (20) therein and including a proximal portion (11) of a second, flexible, radiopaque plastic material and a distal end portion (12) of a first, flexible, radiopaque plastic material having a durometer lower than said second, flexible, radiopaque plastic material, said first, flexible, radiopaque plastic material of said distal end portion comprises a homogeneous plastic composition and/or a thermoplastic elastomer containing a greater weight percent of a radiopaque agent than does the proximal portion, characterised in that the distal end portion contains 75 weight percentage or more of the radiopaque agent.

2. A catheter according to claim 1, wherein the distal end portion includes a preformed pigtail configuration (16), and wherein the distal end portion is connected to the proximal end portion at a location (13) proximal of the said configuration.

3. The catheter of claim 1 or 2, wherein said first radiopaque agent has a density greater than 10 grams per cubic centimeter, or is selected from a group containing tungsten, platinum, gold, silver, lead, and tantalum.

4. The catheter of claim 1, 2 or 3, wherein said second, flexible, radiopaque plastic material comprises an other radiopaque agent selected from bismuth oxychloride, bismuth subcarbonate, bismuth trioxide, barium sulfate, and tungsten.

5. The catheter of claim 1, 2, 3 or 4, wherein said second, flexible, radiopaque plastic material comprises a thermoplastic material from a polyester elastomer, a polyurethane, a polyamide elastomer, and a polyether block amide, or comprises a nylon elastomer.

6. The catheter of claim 1, wherein the homogeneous composition includes a base thermoplastic, elastomer material with a durometer in a range of 25 to 72 on the Shore D scale, or wherein the base thermoplastic, elastomer material is from a group containing a polyether block amide and a polyamide terpolymer material, said base comprising thermo-

plastic, elastomer material having a flex modulus in a range of (23,000 to 75,000 pounds per square inch) 161×10^5 to 525×10^5 Pa.

7. The catheter of claim 1, wherein said first, flexible, radiopaque plastic material has a composite durometer of approximately 47 on the Shore D scale.
8. The catheter of any one preceding claim, wherein said tubular member includes a passage extending longitudinally therein, and a sideport communicating therewith for the passage of dye.

Patentansprüche

1. Aus flexiblem Kunststoffmaterial bestehender Kathether (10), enthaltend:

ein längliches Glied mit einem darin befindlichen Durchlaß (20), einem proximalen Teil (11) aus einem zweiten, flexiblen, strahlenundurchlässigen Kunststoffmaterial und einem distalen Endteil (12) aus einem ersten, flexiblen, strahlenundurchlässigen Kunststoffmaterial mit einer geringeren Durometer-Härte als das zweite, flexible, strahlenundurchlässige Kunststoffmaterial, wobei das erste, flexible, strahlenundurchlässige Kunststoffmaterial des distalen Endteils eine homogene Kunststoffzusammensetzung und/oder ein thermoplastisches Elastomer mit einem größeren prozentualen Gewichtsanteil eines strahlenundurchlässigen Mittels als der proximale Teil enthält, dadurch gekennzeichnet, daß der distale Endteil mindestens 75 Gewichtsprozent des strahlenundurchlässigen Mittels enthält.

2. Katheter nach Anspruch 1, bei dem der distale Endteil eine vorgeformte Schweineschwanzkonfiguration (16) aufweist und der distale Endteil an einer zu dieser Konfiguration proximalen Stelle (13) mit dem proximalen Endteil verbunden ist.
3. Katheter nach Anspruch 1 oder 2, bei dem das erste strahlenundurchlässige Mittel eine Dichte von mehr als 10 Gramm pro Kubikzentimeter aufweist oder aus der Gruppe Wolfram, Platin, Gold, Silber, Blei und Tantal ausgewählt ist.
4. Katheter nach Anspruch 1, 2 oder 3, bei dem das zweite, flexible, strahlenundurchlässige Kunststoffmaterial ein anderes strahlenundurchlässiges Mittel, ausgewählt unter Bismutoxidchlorid, basischem Bismutcarbonat, Bismuttrioxid, Bariumsulfat und Wolfram enthält.
5. Katheter nach Anspruch 1, 2, 3 oder 4, bei dem das

zweite, flexible, strahlenundurchlässige Kunststoffmaterial ein thermoplastisches Material aus einem Polyester-Elastomer, einem Polyurethan, einem Polyamid-Elastomer und einem Polyether-Blockamid oder ein Nylon-Elastomer enthält.

6. Katheter nach Anspruch 1, bei dem die homogene Zusammensetzung ein thermoplastisches, elastomeres Grundmaterial mit einer Durometer-Härte im Bereich von 25 bis 72 auf der Shore-D-Skala enthält oder bei dem das thermoplastische, elastomere Grundmaterial aus der Gruppe Polyether-Blockamid- und Polyamid-Terpolymer-Material ausgewählt ist, wobei es sich bei dem Grundmaterial um thermoplastisches, elastomeres Material mit einem Biegemodul im Bereich von 161×10^5 bis 525×10^5 Pa (23.000 bis 75.000 Pounds pro Quadratzoll) handelt.
7. Katheter nach Anspruch 1, bei dem das erste, flexible, strahlenundurchlässige Kunststoffmaterial eine Verbundwerkstoff-Durometer-Härte von etwa 47 auf der Shore-D-Skala aufweist.
8. Katheter nach einem der vorhergehenden Ansprüche, bei dem das röhrenförmige Glied einen darin in Längsrichtung verlaufenden Durchgang und eine damit in Verbindung stehende Seitenöffnung für den Durchgang von Farbmittel enthält.

Revendications

1. Cathéter en matière plastique flexible (10) comprenant :

un long élément contenant un passage (20) et comportant une partie proximale (11) en une deuxième matière plastique, opaque aux rayons X, flexible et une partie d'extrémité distale (12) en une première matière plastique, opaque aux rayons X, flexible, présentant une dureté au duromètre inférieure à celle de la deuxième matière plastique, opaque aux rayons X, flexible, ladite première matière plastique opaque aux rayons X, flexible de ladite partie d'extrémité distale comprenant une composition de matière plastique homogène et/ou un élastomère thermoplastique contenant un pourcentage en poids d'un agent opaque aux rayons X supérieur à celui de la partie proximale, caractérisé en ce que la partie d'extrémité distale contient 75% en poids ou plus de l'agent opaque aux rayons X.

2. Cathéter suivant la revendication 1, dans lequel la partie d'extrémité distale comprend une configuration préformée en queue de cochon (16), et dans lequel la partie d'extrémité distale est raccordée à

la partie d'extrémité proximale à un endroit (13) proche de ladite configuration.

3. Cathéter suivant la revendication 1 ou 2, dans lequel ledit premier agent opaque aux rayons X possède une masse volumique supérieure à 10 grammes par centimètre cube ou est choisi dans un groupe comprenant le tungstène, le platine, l'or, l'argent, le plomb et le tantale. 5
4. Cathéter suivant la revendication 1, 2 ou 3 dans lequel ladite deuxième matière plastique, opaque aux rayons X, flexible comprend un autre agent opaque aux rayons X choisi parmi l'oxychlorure de bismuth, le sous-carbonate de bismuth, le trioxyde de bismuth, le sulfate de baryum, et le tungstène. 10 15
5. Cathéter suivant la revendication 1, 2, 3 ou 4, dans lequel ladite deuxième matière plastique, opaque aux rayons X, flexible comprend une matière thermoplastique faite d'un élastomère de polyester, d'un polyuréthane, d'un élastomère de polyamide, et d'un amide de polyéther en bloc, ou comprend un élastomère de Nylon. 20 25
6. Cathéter suivant la revendication 1, dans lequel la composition homogène comprend une matière d'élastomère thermoplastique de base, avec une dureté au duromètre dans un intervalle allant de 25 à 72 sur l'échelle de dureté Shore D, ou dans lequel la matière d'élastomère thermoplastique de base est issue d'un groupe contenant un amide de polyéther en bloc et une matière terpolymère de polyamide, ladite base comprenant une matière d'élastomère thermoplastique présentant un module de flexion compris dans l'intervalle de 161×10^6 à 525×10^6 Pa (23 000 à 75 000 livres par pouce carré). 30 35
7. Cathéter suivant la revendication 1, dans lequel ladite première matière plastique, opaque aux rayons X présente une dureté au duromètre composite d'environ 47 sur l'échelle de dureté Shore D. 40
8. Cathéter suivant l'une quelconque des revendications précédentes, dans lequel ledit élément tubulaire contient un passage intérieur s'étendant longitudinalement, et une ouverture latérale communiquant avec celui-ci en vue du passage d'une matière colorante. 45 50

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